

510(k) Summary**Submitter's Name and Address:**

ElscinTEC Systems
MATAM – Advanced Technology Center
Haifa 31905
Israel

Contact Person and Telephone / Fax / E-mail:

Elliot Marshall
(972) 48131403 (phone)
(972) 48131400 (fax)
elliot_marshall@elscintec.co.il

Date of Summary:

November 5, 2000

Device Name:

DIGIMAM Digital Stereotactic Biopsy System Option for GLORY
Mammography System

Classification Name:

Mammographic X-Ray System

In the submission, equivalence is claimed to:

- GLORY Mammography System (with Optional Mammoguide Stereotactic Biopsy System) (K970680)
- MammoVision Digital Imaging System used with Mammotest Stereotactic Needle Biopsy System (Fischer Imaging)

The optional DIGIMAM Digital Stereotactic Biopsy System is intended to be used for stereotactic breast biopsy and needle localization procedures.

The device produces small-field (5 cm x 5 cm) digital images with the Mammoguide Stereotactic Biopsy System. The digital stereotactic application operates in a "Windows® 98" environment from the computer of the Digital Workstation. The Digital Workstation consists of a personal computer, image monitor, mouse, keyboard and optional accessories such as a printer or a digital storage device. The workstation processes, displays, and stores the digital image and communicates information to the mammography system for placing the Mammoguide (robot).

The technological characteristics (with regards to the "spot" digital imaging capabilities of the devices) are compared to a legally marketed device.

PARAMETER	GLORY with DIGIMAM	Mammovision/ Mammotest
CAMERA		
Detector type	CCD	CCD
Phosphor	Min-R screen	Min-R screen
Light transfer	2:1 fiber optic reducer	2:1 fiber optic reducer
Detector size	5 x 5 cm	5 x 5 cm
Detector matrix	1024 x 1024	1024 x 1024
Pixel size	48 microns	48 microns
Pixel depth	14 bits (16384 gray shades)	12 bits (4096 gray shades)
Limiting resolution	10 lp/mm	10 lp/mm
Acquisition and display time	Less than 2.5 sec.	Less than 6 sec.
DISPLAY		
Size	21-inch color monitor	24-inch monochrome monitor
Resolution	1024 x 1280	1024 x 1280

Non-clinical testing with various test phantoms has verified the effectiveness of the DIGIMAM Digital Stereotactic Biopsy System option.

With regards to safety, the GLORY mammography system (including the DIGIMAM Digital Stereotactic Biopsy option) is designed to comply with IEC (International Electrotechnical Commission) International Standards:

60601-1, Medical Electrical Equipment, Part 1: General Requirements For Safety.

Collateral standards:

60601-1-1, Safety requirements for medical electrical systems.

60601-1-2, Electromagnetic compatibility – Requirements and tests.

60601-1-3, General Requirements for radiation protection in diagnostic X-ray equipment.

60601-1-4, Programmable electrical medical systems.

60601-2-32, Particular requirements for the safety of associated equipment of X-ray equipment

60601-2-45, Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 28 2000

Elliot Marshall
Physicist
Elscentec Systems Ltd.
Matam-Advanced Technology Center
Haifa
Israel

Re: K003473
DIGIMAM Digital Stereotactic Biopsy System
Option for Glory Mammography System
Dated: November 6, 2000
Received: November 8, 2000
Regulatory class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Marshall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have ~~been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act)~~. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. ~~Please note: this response to your premarket notification submission does not~~ affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Statement of Indications For Use

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510(k) Number (if known): K003473

Device Name:

DIGIMAM Digital Stereotactic Biopsy System Option for GLORY
Mammography System

Indications For Use:

Stereotactic biopsy and preoperative wire localization procedures

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Donald C. Peterson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003473